

EXPEDITED REVIEW PROCEDURES

1. Overview

The IRB Chair or one or more experienced IRB members designated by the Chair may use expedited review procedures to approve a limited class of research activities involving human subjects. Expedited IRB review procedures may be used for the following:

- Initial or continuing review of specific categories of research not greater than minimal risk
- Continuing review of research previously approved by the convened IRB, under specified circumstances
- Review of minor changes to previously approved research.

This policy describes the situations in which research may qualify for expedited review, as well as the process by which the IRB reviews research by expedited procedures.

2. Definitions

Annual Status Report: Under certain conditions, the requirements for continuing IRB review can be satisfied through the completion of a brief application confirmed by a designated ORRP staff member through an administrative review. The abbreviated application is available for minimal risk, expedited studies that are not FDA-regulated or federally funded.

Expedited Review: Process by which designated IRB members, on behalf of the full IRB, approve a limited class of research activities through reviews conducted outside of the convened IRB meeting.

Expedited IRB Reviewer: The IRB Chair and those experienced IRB members designated by the Chair who may perform some or all types of expedited reviews.

Experienced IRB Member: An IRB member determined by the IRB Chair to be qualified to perform reviews using expedited procedures. The following criteria are considered when determining whether an IRB member is experienced: length of IRB service (at Ohio State and/or at a previous institution), training regarding expedited review procedures, research experience/expertise, and/or work with the research participants being studied.

Minor Changes: Changes to research that in the judgment of the IRB do not affect assessment of the risks and benefits of the study by substantially altering any of the following: research aims or methodology, nature of subject participation, level of risk, proposed benefits, participant population, qualifications of the research team, or the facilities available to support the safe conduct of the research. *Note: A minor change does not increase risk more than minimally or add procedures in research categories other than those that qualify for expedited initial review.*

For specific examples of changes that may be considered minor (and may be reviewed using expedited procedures), see Attachment 1.



3. Research Eligible for Expedited Review

- A.** Research activities that present no more than minimal risk to human subjects and involve only procedures listed in one or more of the categories in *Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure* (see Attachment 2) may be reviewed by the IRB through the expedited review procedure.
- B.** Expedited review procedures may be used for initial or continuing review of research that presents no more than minimal risk to human subjects in categories (1) through (7) in *Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure* (see exceptions below).
- C.** Continuing review of research previously approved by the convened IRB may receive expedited review in any of the following situations:
- The research is permanently closed to enrollment, all participants have completed all research-related interventions, and the research remains active only for long-term follow-up.
 - No participants have been enrolled and no additional risks have been identified.
 - The remaining research activities are limited to data analysis.
- D.** The expedited procedure may also be used for continuing review of research that does not fit categories (1) through (7) or the conditions described above, when:
- The research is not conducted under an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE), and
 - The IRB has determined and documented at a convened meeting that the research involves not greater than minimal risk and no additional risks have been identified.
- E.** Unless the IRB requires that a study undergo continuing review, researchers can submit an annual status report to be administratively reviewed and confirmed by a designated ORRP staff person. Qualifying studies must meet all of the following conditions:
- Studies considered minimal risk and qualifying for expedited review even if the study initially received convened review
 - Studies not supported by a federal agency or not having received federal funding at *any* time during the research, including through a sub-award from another institution
 - Studies not FDA-regulated including studies involving drugs, devices, and data submission
 - The investigators do not intend to make personnel changes at the time of the annual review.

Please Note: An annual status report undergoes administrative review which is different from, and does not satisfy the requirements of, continuing review. If an ongoing study receives federal funding, adds drugs or devices, or includes new procedures that increase participant risk to greater than minimal, an amendment must be submitted for IRB review and approval to reset the research expiration date and to place the study back into continuing review status.



- F. Minor changes (amendments) to previously approved research during the period for which approval is authorized (one year or less) may be reviewed using expedited procedures.
- G. Requirements for informed consent (or for waiver, alteration, or exceptions to the requirements for informed consent) apply regardless of whether the research is reviewed by the convened IRB or by an expedited procedure.
- H. The expedited review procedure may not be used to review research in which identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are not greater than minimal.
- I. Expedited review procedures may not be used for classified research involving human subjects.
- J. The specific circumstances of the proposed research must be considered when determining that the research involves no more than minimal risk to human subjects. The activities listed in *Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure* should not be considered minimal risk simply because they are included on the list.
- K. Additions to or extrapolations from the list of activities included in *Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure* are not appropriate. Expedited review procedures may not be used unless the proposed research activities appear on the list, even when the research presents no more than minimal risk.

4. Submission Requirements

- A. When submitting applications in Buck-IRB for initial or continuing review using the expedited procedure, investigators must submit all applicable materials listed in HRPP policy [[IRB Submission and Pre-Review](#)].
- B. When submitting applications in Buck-IRB for annual status reports using an expedited administrative review procedure, the annual report is limited to questions regarding study changes over the previous year and the current study status. No additional materials need to be submitted with the report.
- C. When submitting amendment requests in Buck-IRB for expedited review, investigators must submit all applicable materials (clean and revised copies of modified documents, clean copy of newly proposed document(s) being added) listed in HRPP policy [[IRB Submission and Pre-Review](#)].
- D. Upon receipt of an application for expedited review, an ORRP staff member pre-reviews the submission (e.g., to verify whether the materials are complete) and makes an initial determination as to whether the submission is eligible for expedited review.



5. Expedited Reviewer Assignments

- A. ORRP staff members assign expedited reviews to one or more IRB members from the pool of experienced reviewers designated by the IRB Chair (which may also include the IRB Chair).
- B. When making expedited reviewer assignments, the ORRP staff member also considers the following:
- Reviewer's scientific and/or scholarly expertise
 - Reviewer experience
 - Reviewer's status as scientist or nonscientist
 - Reviewer workload
 - Potential conflicts of interest (both financial and personal/professional as defined in HRPP policy [[IRB Member and Consultant Conflict of Interest](#)])
 - The need for special representation (e.g., vulnerable populations).

ORRP staff members consult with the IRB Chair as necessary when making reviewer assignments.

- C. ORRP staff notify IRB members of review assignments and confirm reviewers' availability and eligibility (e.g., no conflicting interests) to perform timely reviews.

6. Expedited Review Procedures

A. Initial and Continuing Review

1. Assigned reviewer(s) will receive all information that the convened IRB would have received and will initially review the materials submitted to confirm that the research meets the applicability criteria and one or more categories of research eligible for expedited review.
2. For continuing review, the complete protocol file and relevant minutes from previous IRB review(s), as applicable, will also be available upon request.
3. The expedited reviewer(s) will perform an in-depth review of all submitted materials, using the criteria for approval described in federal regulations and HRPP policy [[Review of Research by the Convened IRB](#)].
4. For continuing review, reviewer(s) will also determine the following:
 - Whether the protocol needs verification from sources other than the investigators that no material changes occurred since previous IRB review, as described in HRPP policy [[Review of Research by the Convened IRB](#)]
 - That the current consent document is still accurate and complete
 - Any significant new findings that arise from the review process and that may relate to subjects' willingness to continue participation will be provided.
5. The expedited reviewer(s) will complete the applicable *IRB Reviewer Sheet*. Reviewer(s) will document the specific category or categories under which the research qualifies for expedited review and any finding(s) required by regulations, including protocol-specific information justifying the finding(s).



6. Research that does not meet the criteria for expedited review in the judgment of the IRB reviewer(s) will be forwarded to the next available meeting of the convened IRB.

B. Minor Changes (Amendments) to Previously Approved Research

1. Assigned reviewer(s) will receive all information that the convened IRB would have received and will initially review the materials submitted to confirm that the amendment meets the criteria (i.e., a minor change) for expedited review.
2. The complete protocol file and relevant minutes from previous IRB review(s), as applicable, will also be available for review upon request.
3. The expedited reviewer(s) will perform an in-depth review of all submitted materials, using the criteria for approval described in federal regulations and HRPP policy [[Review of Research by the Convened IRB](#)] when the modifications affect one or more regulatory criteria.
4. The reviewer(s) will also determine that any significant new findings that arise from the review process and that might relate to subjects' willingness to continue participation will be provided.
5. The expedited reviewer(s) will complete the applicable *IRB Reviewer Sheet*. Reviewer(s) will document that the amendment represents a minor change(s) qualifying for expedited review and any finding(s) required by regulations, including protocol-specific information justifying the finding(s).
6. Research that in the judgment of the IRB reviewer(s) does not meet the criteria for expedited review (i.e., more than a minor change) will be forwarded to the next available meeting of the convened IRB.

7. Outcomes of Expedited Review

- A.** When reviewing proposed research activities using expedited procedures, IRB reviewers may take one of the following actions:

- Approved
- Modifications required (to secure approval).

An expedited reviewer can also request additional information and/or clarification from the investigator before taking one of the above actions.

- B.** When an expedited reviewer cannot take one of the actions above, the research will be referred for review by the convened IRB. Reviewers may not disapprove research by expedited review. Research can be disapproved only following review by the convened IRB as described in federal regulations and HRPP policy [[Review of Research by the Convened IRB](#)].

- C.** Research will be forwarded to the convened IRB for review when any of the following occur:

- Expedited reviewer(s) cannot determine that the research meets the criteria for expedited review
- Expedited reviewer(s) cannot approve the research or require modifications in the research to secure approval



- Expedited reviewer(s) cannot approve the research for one year, based on the criteria described in HRPP policy [[Review of Research by the Convened IRB](#)]
- Expedited reviewers (if more than one) cannot reach a consensus decision during the review process.

D. When an expedited reviewer refers research for convened IRB review, the submission materials, reviewer's comments, and any additional information obtained from the investigator are forwarded for consideration at the next available IRB meeting.

8. Review of Investigator Responses

- A. When expedited reviewer(s) require modifications to research, investigators' responses will be reviewed as described in HRPP policy [[IRB Actions and Communications](#)] to verify that the conditions for approval have been satisfied. Depending on the nature of the modifications, this subsequent review/verification may be performed by the IRB Chair, one or more IRB members or a consultant with specific expertise, and/or qualified ORRP staff (who may or may not be IRB members).
- B. Questions about whether the conditions for approval have been satisfied will be forwarded to the IRB Chairs or Vice-Chairs. When the conditions for approval cannot be met, the submission will be referred to the convened IRBs for review (i.e., research cannot be disapproved except by convened review).
- C. For expedited initial review and review of amendments, the approval date of the research is the date that the IRB Chair, IRB member(s), consultant, and/or ORRP staff member verifies that the conditions for approval have been met. However, for continuing review, the approval date is the date the modifications were required by the expedited reviewer(s).
- D. For specific examples of investigators' responses that can be administratively reviewed by ORRP staff, see HRPP policy [[IRB Actions and Communications](#), Attachment 1].

9. Communicating Expedited Review Actions

- A. Investigator Correspondence
1. ORRP staff will notify the principal investigator electronically of the action taken by the expedited reviewer(s) and any modifications required as a condition for IRB approval. Notifications of IRB approval by expedited procedures will include the specific category or categories under which the research qualifies for expedited review (as applicable).
 2. When an expedited reviewer refers a submission for convened IRB review, the principal investigator will be notified of the referral and the scheduled convened meeting date.
- B. Notification of IRB Members and Institutional Officials

IRB members and institutional officials are notified of all research that is approved by expedited review procedures. Actions and findings are documented in a summary that is posted and can be printed from the HRPP secure websites.



10. Record Retention

Records of research undergoing expedited review, including materials submitted and related correspondence, are retained by the Office of Responsible Research Practices in accordance with HRPP policy [[IRB Recordkeeping](#)]. Records will include the expedited category or categories under which determinations were made, as applicable, and any finding(s) required by regulations, including protocol-specific information justifying the finding(s).

11. Applicable Regulations/Guidance

21 CFR 56.110, 45 CFR 46.110, "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure" (63 FR 60364-60367, 11/09/98), OHRP "Guidance on IRB Continuing Review of Research" (11/10/10), OHRP "Guidance on IRB Approval of Research with Conditions" (11/10/10), OHRP "Guidance on the Use of Expedited Review Procedures" (08/11/03), OHRP "Guidance on Written IRB Procedures" (07/01/11).

12. History

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12/19/2016

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**Attachment 1.
Minor Changes to Approved Research**

Minor changes to research are those that in the judgment of the IRB do not affect assessment of the risks and benefits of the study by substantially altering any of the following:

- Research aims or methodology
- Nature of subject participation
- Level of risk
- Proposed benefits
- Participant population
- Qualifications of the research team
- Facilities available to support the safe conduct of the research.

A minor change does not increase risk more than minimally or add procedures in research categories other than those that qualify for expedited initial review.

Examples of changes to previously approved research that may be considered minor (and may be reviewed using expedited procedures) when they do not alter the risk/benefit ratio include:

1. Changes in study documents, such as recruitment materials, consent forms, questionnaires, etc. that do not materially affect participation of the subject in the study or alter the meaning of the text (e.g., formatting, phone or room numbers, etc.).
2. Clarifications of the study protocol, procedures, or consent language that do not introduce new procedures or information.
3. Changes in wording or deletions of a question(s) on a survey or in the material properties of a stimulus, where the change or deletion does not alter the fundamental meaning of the item for the research or change the nature of the subject's participation in the study.
4. Addition of a standardized survey instrument that does not substantially increase risk to participants or the duration of their study participation.
5. Addition of advertisements or recruitment materials that are not considered coercive and are easily compared to the approved informed consent script or document.
6. Increases in numbers of participants, who are identified and recruited by approved methods from currently approved populations, or increases in local site enrollment in multi-site studies where the increase does not exceed the approved total number of participants across all sites.
7. Decreases in number or frequency of data collection points that do not compromise study integrity or decrease safeguards for participants.
8. Changes in data handling, storage, or security that maintain a similar or increased level of confidentiality protections for the study data.
9. Changes in incentives for adult participants that are not considered coercive, do not present undue influence, and are not contingent upon completion of the entire study.
10. Changes in investigators or research staff with similar or greater qualifications to perform or assist in the research.
11. Addition of new study sites that are not substantially different (e.g., qualifications of study personnel, research environment, etc.) than those already approved for the research.
12. Addition of translations of previously approved materials.

**Attachment 2.****Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure*****Applicability***

(A) Research activities that present no more than minimal risk to human subjects and involve only procedures listed in one or more of the following categories may be reviewed by the IRB through the expedited review procedure. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review – expedited or convened – utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a. Research on drugs for which an investigational new drug application (21 CFR 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b. Research on medical devices for which an investigational device exemption application (21 CFR 812) is not required or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. Samples from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
 - b. Samples from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml/kg in an 8-week period and collection may not occur more frequently than 2 times per week.



3. Prospective collection of biological specimens for research purposes by noninvasive means.
Examples:
 - a. Hair and nail clippings in a non-disfiguring manner
 - b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
 - c. Permanent teeth if routine patient care indicates a need for extraction
 - d. Excreta and external secretions (including sweat)
 - e. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue
 - f. Placenta removed at delivery
 - g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
 - h. Supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
 - i. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
 - j. Sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:
 - a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy
 - b. Weighing or testing sensory acuity
 - c. Magnetic resonance imaging
 - d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
 - e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes, such as medical treatment or diagnosis. (Note: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the DHHS



regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
 - a. Where the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects; or
 - b. Where no subjects have been enrolled and no additional risks have been identified;
or
 - c. Where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.